

REMARKS/ARGUMENTS

In the Claims, please cancel Claims 7-9, 13, 34-43 and 49-54 without prejudice. Claims 1, 14, 15, 45 and 46 have been amended in response to the Examiner's rejections. New Claims 55 and 56 have been added. The amendments to the claims are fully supported by the Application as originally filed on page 4, paragraph 0063. New claims 55 and 56 are fully supported on page 5, paragraph 0076. No new matter has been added.

Rejection Under 35 U.S.C. § 112

Claims 1-15 and 34-54 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement due to the limitation of "a substantially air and moisture impermeable seal". This limitation has been removed from independent claim 1 (and therefore also its dependent claims). Claim 34 has been cancelled.

Rejections Under 35 U.S.C. § 103

A. Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 6,029,659 to O'Connor ("O'Connor") in view of US Patent No. 5,544,647 to Jewett ("Jewett"). Claims 7-9 have been cancelled.

In order to establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *See* MPEP, § 2143.03 ("MPEP"); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580.

Claim 1 has been amended to include the limitation of "a ramp" that is contacted by the ferrule portion of the canister and "which acts upon the switch means when the canister is moved in the first

direction." Neither O'Connor nor Jewett discloses a "ramp" which is acted upon by the ferrule and which acts upon the switch means. Not only is this limitation not disclosed in either of the references, but the ramp design of the present invention has a novel and distinct advantage over other types of structures and switches that trigger electronic dose counters. As disclosed in the specification from paragraph 0075 through paragraph 0080 of the specification, the ramp 42 is acted on by the ferrule portion of the canister, which displaces the elastomeric or trigger seal 36 and triggers the dose count before the medication is dispensed. The canister ferrule contacts the ramp which closes the switch and triggers the count. As the canister ferrule continues to travel over the ramp (which is permitted due to its unique shape and design, see page 6, paragraphs 0078 and 0079), at some point thereafter the valve opens (dispensing the medication). The time difference between the switch closing and the valve opening is called "lag" and this lag time ensures that no medicament is dispensed without a "count" in the dose counter. This is extremely important in ensuring that the patient does not run out of medication because the apparatus was accidentally triggered without counting the dose(s) dispensed (see page 5, paragraph 0075).

This "ramp" limitation is not taught in either O'Connor or Jewett, nor is there any suggestion in either piece of art to modify or combine the art such that it would include a "ramp" design. Jewett teaches the closing of an internal or external microswitch that triggers the microelectronic means to subtract "one" from the visual indicia count shown. However, Jewett uses a "dome" switch. The specification of the present invention discusses the problems inherent with a dome switch at col. 5, lines 1-8. As a result, a person skilled in the art would not have been motivated, nor is there any teaching or suggestion in the art, to modify Jewett's microswitch design to arrive at the "ramp" design of the present invention.

Further, the Applicant respectfully disagrees that a person of ordinary skill in the art would be motivated to modify the device of O'Connor to include the switch activation means of Jewett in order to provide adequate visual confirmation of the medication count, battery failure, etc. The type of switch used

in a dose counter is not indicative of whether or not the patient has the ability to visually confirm the amount of medication doses that are remaining. Such visual indicia is inherently a requirement of a dosage counter, and O'Connor already has visible display 41 of counter 40 for the patient's visual confirmation (Col. 7, lines 1-2).

As for claims 2-4 and 6, for the reasons stated above, the Applicant respectfully disagrees that the invention is obvious over O'Connor in view of Jewett. Further, neither reference teaches the number of doses taken in a dosage sequence. O'Connor, at column 5, lines 5-25, teaches that the visual display can be "reenergized" by using more than one button or multiple contact points in a single switch. Thus, a patient whose visual display had "timed out" for energy conservation could press a first button, or the switch to a "first point" in order to (1) reenergize the visual display, which would show "the current number of doses administered", and then press a second button or press the same switch to the "second point" in order to (2) increment the counter as the dose is administered. This discloses merely dose counting by incrementing the counter one time per dose administered, O'Connor does not disclose a dosage sequence mode such as counting "actuation 1 of a total of 3" (page 3, paragraph 55).

Claims 7-9 have been cancelled.

B. The Examiner rejects Claims 10-15 under § 103(a) as being unpatentable over O'Connor in view of Jewett and further in view of U.S. Patent No. 6,431,168 to Rand et al. ("Rand"). Rand teaches a switch means 44 with an electrically conductive contact members 46/47. As discussed above, there is no teaching or suggestion in either O'Connor or Jewett, either alone or in combination, to alter the switch means to a "ramp" design. Further, there is not motivation or teaching in Rand to alter the switch design, regardless of the use of electrically conductive contacts 46/47. Even if the electrically conductive contacts were combined with the microswitch disclosure of Jewett, there is no teaching or suggestion of the "ramp"

design of the present invention, to trigger the dose counter and medicament dispensation. As a result, the Applicant respectfully submits that claims 10-15 are not obvious over these three references.

C. Claims 34-37 and 39, 40, 42, 44-54 are rejected under § 103(a) as being unpatentable over O'Connor and Jewett and further in view of Rand. Claims 34-44, and 49-54 have been cancelled. Only claims 45-48 remain, and these claims depend from claim 1, which was amended to add the "ramp" limitation. As discussed above, this limitation is not taught or suggested by any of O'Connor, Jewett, or Rand, alone or in combination. As a result, the Applicant respectfully provides that the rejection is moot.

Based on the amendments and remarks set forth above, the Applicant hereby respectfully requests that the Examiner's rejections be withdrawn and that the Application is in condition for allowance. Should the Examiner have questions or require additional information or clarification, please do not hesitate to contact the Applicant's undersigned attorney. Please charge any required fees to our Deposit Account No. 50-2543.

Respectfully submitted,


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